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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	P-LJ-3578	8259

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EXAMINER

HUNT, JENNIFER ELIZABETH

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/350,518

Applicant(s)

Reed et al.

Examiner

Jennifer Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 12, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 11-14, 16, 18-27, 29-37, and 44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 11-14, 16, 18-27, 29-37, and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. Acknowledgment is made of applicant's cancellation of claims 9, 10, and 15. Claims 6-8, 11-14, 16, 18-27, 29-37, and 44 are pending in the application and considered herein.

Claim Rejections Withdrawn

2. The rejection of claims 6-16, 19-27, 29-37, and 44 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for being enabling for detecting increased BAG-1 (*the truncated form taught in Takayama et al., Cancer Research, Vol 38, page 3116, abstract*) as an indicator of increased overall survival or distant metastasis free survival in Stage I or Stage II breast cancer patients, but not for detection of an increase or decrease in any and all BAG gene expressions as an indicator of prognosis, risk of recurrence, risk of metastasis, or monitoring treatment effectiveness for any and all cancer is withdrawn in light of applicant's amendments, and further in light of the new grounds of rejection set forth below.

New Grounds of Rejection

3. Claims 6-8, 11-14, 16, 18-27, 29-37, and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting increased BAG-1 expression in breast cancer tissue, detected using immunohistochemical staining, as an indicator of increased overall survival or distant metastasis free survival in Stage I or Stage II breast cancer

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patients, is not enabling for detection of an increase or decrease in BAG-1 gene expression in breast cancer tissue or body fluid, or further as an indicator of prognosis, risk of recurrence, risk of metastasis, or monitoring treatment effectiveness.

The claims are broadly drawn to a method of detecting stage I or II breast cancer by detecting BAG protein or mRNA expression in a tissue or body fluid.

The specification discloses that increased levels of BAG-1 gene expression in breast cancer tissue samples, using a monoclonal antibody to the isoform BAG-1 (a truncated form of the full protein) predicts increased overall survival or distant metastasis free survival in patients with Stage I or Stage II breast carcinoma.

The prior art teaches that in many cancers, increased BAG expression in cancerous tissue is correlated with poor prognosis and increased risk of distant metastasis and tumor recurrence. *Tang et al., Journal of Clinical Oncology, Vol 17, No 6, pages 1710-1719, (June 1999)* teaches that increased BAG-1 expression was significantly associated with shorter disease free and overall survival in all stages of breast cancer (table 4, page 1718). Further, *Zapata et al., Breast Cancer Research and Treatment, Vol 47, pages 129-140 (1998)* teaches that BAG-1 levels are higher in invasive breast cancers (page 138, 1st column, 3rd paragraph). *Yawata et al., Oncogene, Vol 16, pages 2681-2686 (1998)* teaches that increased BAG-1 levels promote metastasis in colon cancer (abstract and page 2681, 2nd column, last paragraph). Additionally, *Takaoka et al., Oncogene, Vol 14, pages 2971-2977 (1997)* teaches that over expression of BAG-1 promotes pulmonary metastasis of melanoma (abstract). The art does not teach detection of

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BAG-1 in body fluid, or in any other medium except immunohistochemical detection from cancerous tissue.

Therefor the art teaches that increased levels of BAG expression do not indicate decreased risk of metastasis or recurrence for cancer. Similarly, detection of the different isoforms of BAG have lead to differing conclusions about breast cancer prognosis.

Further, BAG-1 is disclosed to be a cytosolic or nuclear protein, and all of the teachings in the instant specification and in the prior art are drawn to immunohistochemical detection of BAG-1 in tissue. Detection of a cytosolic protein or a nuclear protein does not support the suggestion that the protein also will be shed into body fluids, and in particular does not provide the suggestion that the protein will be shed into a body fluid in sufficient quantities to be diagnostic for breast cancer. Therefor absent guidance or objective evidence as to the extracellular detection and diagnostic qualities of BAG-1 in body fluid, one of skill in the art would not be enabled to practice the full scope of the invention commensurate in scope with the claims, because there is no guidance or objective evidence that BAG-1 is detectable in body fluid, or further, that if it is detectable in body fluid, that BAG-1 levels would correlate to a diagnosis of breast cancer.

Thus because the art sets forth specific examples in which the full scope of the instant claims are not enabled, and due to the lack of guidance or objective evidence in the specification to support detection of an increased risk of metastasis, or reoccurrence, or detection in body

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fluids, one of ordinary skill in the art at the time the invention was made would not have been enabled to practice the full scope of the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set

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forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OF 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

June 30, 2002


SHEELA HUFF
PRIMARY EXAMINER